

Remarks

The non-final Office Action dated July 7, 2009, has been reviewed and following remarks are made in response thereto. In view of the following remarks, Applicants respectfully request reconsideration of this application and timely allowance of the pending claims. Claims 1-23 are pending.

Rejections under 35 U.S.C. § 103

In order to meet its burden in establishing a rejection under 35 U.S.C. § 103, the office action must first demonstrate that the combined prior art references teach or suggest all the claimed limitations. See *Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342 (Fed. Cir. 2007) ("the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make [every element of] the composition or device, or carry out the [entire] claimed process, and would have had a reasonable expectation of success in doing so," (citing *KSR Int'l Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1395 (US 2007).) "Subsumed within the Graham factors is a subsidiary requirement articulated by this court that where, as here, all claim limitations are found in a number of prior art references, the burden falls on the challenger of the patent to show by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." (*Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007) (citing *DyStar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 1360 (Fed. Cir. 2006).) As such, a finding of obviousness at least requires that all of the claim elements be taught or suggested in the cited art.

In addition, obviousness can be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so. (*In re Kahn*, 441 F.3d 977, 986 (Fed. Cir. 2006).) The mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art. (*KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007).) "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." (KSR, 550 U.S. at ___, 82 USPQ2d at 1396 quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).) Thus the office action must put forth some objective reason for combining the

teachings of the cited references in order to establish obviousness. (See, e.g., MPEP § 2143.01.) Thus the office action must put forth some objective reason for combining the teachings of the cited references in order to establish obviousness. (See, e.g., MPEP § 2143.01.)

Furthermore, the office action must rely on analogous art. "Under the correct analysis, any need or problem known in the field of endeavor at the time of the invention and addressed by the patent [or application at issue] can provide a reason for combining the elements in the manner claimed." (KSR, 550 U.S. 398.) Thus a reference in a field different from that of applicant's endeavor is not reasonably pertinent if it is one which, because of the matter with which it deals, logically would not have commended itself to an inventor's attention in considering his or her invention as a whole. (See MPEP § 2141.01(a).)

a. Combination of *Berger, Thompson, and Samejima*

Claims 1-23 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Berger et al.* (US 4,470,975) ("Berger") and *Thompson et al.* (US 5,004,603) ("Thompson") in view of *Samejima et al.* (EP 0077956) ("Samejima"). Applicants respectfully traverse the rejection.

Applicants respectfully submit that the cited references do not provide for direct administration of a water absorbent polymer, that is capable of absorbing at least 10 times its weight in physiological saline, as an active agent to the intestinal tract for increasing the fluid in the feces. The Examiner states that "one of ordinary skill in the art would have had a reasonable expectation of success" of preventing disintegration of the polymers in the stomach because "Berger, Thompson, and Samejima teach[] a composition that can be used in the same [field] of endeavor, such as successfully removing excess fluid or water in a body by administering an effective amount of a water-absorbing polymer to the host." (Office Action at pages 5-6.) Applicants respectfully disagree with the Examiner's statement, but if the statement was correct, it does not establish obviousness as required by MPEP § 2143. The mere possibility that two references could be used in the same field of endeavor does not represent an objective reason for combining the teachings of the cited references. (See MPEP § 2143.01; *Ex parte Levingood*, 28 USPQ2d 1300.) In addition, in this case, not all the references are in the same field of endeavor.

The Examiner acknowledges that *Berger* does not disclose direct delivery of polymers to the intestinal tract. (Office Action at pages 3-4.) The Examiner relies on *Thompson* for the teaching of a water absorbent polymer that is capable of absorbing at least 10 times its weight

in physiological saline. (Office Action at page 7.) Applicants respectfully submit, however, that one of skill in the art would not consider the teachings in *Thompson* because it is not analogous art. *Thompson* discloses the use of pre-swollen polymers to help a ruminant livestock absorb more nitrogen from their food, enhance feed conversion rates, and lower the effective cost of feeding the animals. (*Thompson*, Abstract.) Thus *Thompson* is not reasonably pertinent because improving nitrogen absorption, enhancing feed conversion rates, and lowering the effective cost of feeding animals does not logically commend itself to the Applicants' attention in considering the presently claimed invention as a whole. (See MPEP § 2141.01(a).)

Even if *Thompson* were analogous art, however, Applicants respectfully submit that one of skill in the art would not be motivated to combine the teachings of *Thompson* with the disclosure of *Berger* because these references use water absorbent polymers for vastly different purposes. In *Berger* the water absorbent polymer is used to absorb water from the gastrointestinal tract, while in *Thompson* the water absorbent polymer, which is at least partially pre-swollen with water, is used to help a ruminant livestock absorb more nitrogen from their food, enhance feed conversion rates, and lower the effective cost of feeding the animals. (*Thompson*, Abstract.)

Samejima describes the delivery to the intestinal tract of enterically coated microcapsules that are used to deliver active core materials. (*Samejima*, page 3, lines 11-16.) Notably, the water-swellable polymer of *Samejima* swells and causes the microcapsules to break open thus releasing an active agent in the intestinal tract. (*Samejima*, page 4, lines 21-40.) Since the water-swellable polymer in the enterically coated microcapsules of *Samejima* was not used as an active agent, had limited absorption capacity and was used only as an aid for dispersing the active agent, a skilled artisan would not be motivated to directly deliver the water absorbent polymer of *Berger* or *Thompson* as an active agent to arrive at the instantly claimed invention. In addition, Applicants respectfully submit that no motivation existed at the time of the instant invention for enterically coating the polymers of *Berger* or *Thompson*. Nothing in either reference suggests enteric coating of the polymer of *Berger* or *Thompson* in order to directly deliver it to the intestinal tract of the host. As such, there is no reason to assume, as the Examiner has done at page 4, that enterically coating the polymer of *Berger* or *Thompson* would have been considered at the time of the instant invention.

In addition, Applicants respectfully submit that, even if one skilled in the art were motivated to combine *Berger*, *Thompson*, and *Samejima* as suggested by the office action, the resulting combination would not result in the invention as claimed. For example, *Berger*

discloses orally administering water-absorbing polymers administered as a suspension in mineral oil. (*Berger*, col. 6, lines 30-32.) *Thompson* discloses orally administering pre-swollen water-insoluble polymers to ruminants through foodstuff. *Samejima* discloses enteric coatings comprising a water-swellable polymer component to improve the porosity of enteric coatings in the intestine. Combining these three references as suggested by the examiner would not result in a method for increasing fluid loss through the feces in a host, comprising the step of directly administering to the intestinal tract of the host an effective amount of a water-absorbent polymer for increasing the fluid in the feces, wherein the water-absorbent polymer is capable of absorbing at least 10 times its weight in physiological saline as claimed in Claim 1 of the present application.

For the above-mentioned reasons, one of skill in the art would not have been motivated to combine the *Berger*, *Thompson*, and *Samejima* references as suggested by the Examiner. Furthermore, the *Berger*, *Thompson*, or *Samejima* references, taken singly or in combination, do not provide or suggest directly delivering to the intestinal tract a water absorbent polymer that is capable of absorbing at least 10 times its weight in physiological saline. Further, even if combined these references would not provide or suggest direct delivery of a water absorbent polymer to the intestinal tract. Given that all of the elements in independent claim 1 (from which claims 2-23 depend) are neither taught nor suggested by *Berger*, *Thompson*, and *Samejima*, the instant claims cannot be obvious. Accordingly, Applicants respectfully request that the rejection of claims 1-23 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

b. Combination of Yonekawa and Samejima

Claims 1-23 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Yonekawa et al.* (JP H10-13154) ("Yonekawa") in view of *Samejima*. Applicants respectfully traverse the rejection.

Applicants respectfully request clarification concerning the references cited by the Examiner in this rejection. The claims were rejected as being unpatentable over *Yonekawa* in view of *Samejima*, however, the Examiner references "the *Berger* and *Thompson* combination" and "*Berger*, *Thompson* and *Samejima*" on page 7. Applicant's arguments below are based on the assumption that the caption of the rejection correctly stated the rejection was based on the combination of *Yonekawa* and *Samejima* only.

The Examiner states that "one of ordinary skill in the art would have had a reasonable expectation of success" of preventing disintegration of the polymers in the stomach because the

cited references "teach[] a composition that can be used in the same [field] of endeavor, such as successfully removing excess fluid or water in a body by administering an effective amount of a water-absorbing polymer to the host." (Office Action at pages 7-8.) Applicants respectfully submit that, even if true, this does not establish obviousness as required by MPEP § 2143. The mere possibility that two references could be used in the same field of endeavor does not represent an objective reason for combining the teachings of the cited references. (See MPEP § 2143.01; *Ex parte Levengood*, 28 USPQ2d 1300.)

The Examiner acknowledges that *Yonekawa* does not disclose direct delivery of polymers to the intestinal tract of a host. (Office Action at page 6.) The Examiner relies on *Samejima* for teaching direct delivery of swellable polymers to the intestinal tract of a host.

Samejima describes the delivery to the intestinal tract of enterically coated microcapsules that are used to deliver active core materials. (*Samejima*, page 3, lines 11-16.) Notably, the water-swellable polymer of *Samejima* swells and causes the microcapsules to break open thus releasing an active agent in the intestinal tract. (*Samejima*, page 4, lines 21-40.) The water-swellable polymer in the enterically coated microcapsules of *Samejima* was not used as an active agent (*Samejima*, page 12, lines 10-23), had limited absorption capacity (e.g., 1.2 to 1.5 times its weight; *Samejima*, page 5, line 22 to page 6, line 9), and was used only as an aid for dispersing the active agent (*Samejima*, page 12, lines 10-23).

Applicants respectfully submit that no motivation existed at the time of the instant invention for enterically coating the polymers of *Yonekawa*. Nothing in *Yonekawa* or *Samejima* suggests enteric coating of the polymer of *Yonekawa* in order to directly deliver it to the intestinal tract of the host. As such, there is no reason to assume, as the Examiner has done at page 6, that enterically coating the polymer of *Yonekawa* would have been considered at the time of the instant invention.

Accordingly, for the above-mentioned reasons, Applicants respectfully request that the rejection of Claim 1 under 35 U.S.C. § 103(a) in light of *Yonekawa* and *Samejima* be reconsidered and withdrawn. Claims 2-23 each depend ultimately from Claim 1; Applicants respectfully request that the rejection of Claims 2-23 be reconsidered and withdrawn in light of the arguments presented above with respect to Claim 1.

Conclusion

Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same. The Examiner is respectfully requested to

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telephone the undersigned to assist in any way in expediting prosecution of this application. The Commissioner is authorized to charge any underpayment of fees or credit any overpayment of fees to Deposit Account No. 02-1818 (order no. 3716444.00011) for any matter in connection with this response.

Respectfully submitted,
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